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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/258,217	02/26/99	KEATING	M 2323-127

HM22/0516

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EXAMINER	
CHEN, S	
ART UNIT	PAPER NUMBER
1633	16

DATE MAILED: 05/16/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Advisory Action

Application No.	Applicant
09/258,217	Keating et al.
Examiner	**Art Unit**
Shin-Lin Chen	1633

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED *Apr 27, 2001* FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid the abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

THE PERIOD FOR REPLY [check only a) or b)]

a) ☒ The period for reply expires *4* months from the mailing date of the final rejection.

b) ☐ In view of the early submission of the proposed reply (within two months as set forth in MPEP § 706.07 (f)), the period for reply expires on the mailing date of this Advisory Action, OR continues to run from the mailing date of the final rejection, whichever is later. In no event, however, will the statutory period for the reply expire later than SIX MONTHS from the mailing date of the final rejection.

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on _____. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.

2. ☐ The proposed amendment(s) will be entered upon the timely submission of a Notice of Appeal and Appeal Brief with requisite fees.

3. ☒ The proposed amendment(s) will not be entered because:

   (a) ☒ they raise new issues that would require further consideration and/or search. (See NOTE below);

   (b) ☐ they raise the issue of new matter. (See NOTE below);

   (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or

   (d) ☐ they present additional claims without cancelling a corresponding number of finally rejected claims.

   NOTE: *The phrase "a genome with a) an elastin gene comprising a null mutation and b) no functional elastin gene" in claims 2 and 4 raises 112 second paragraph indefiniteness issue. A null mutation in an elastin gene leads*

4. ☐ Applicant's reply has overcome the following rejection(s):

5. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in separate, timely filed amendment cancelling the non-allowable claim(s).

6. ☒ The a) ☐ affidavit, b) ☐ exhibit, or c) ☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because:
The claims remain rejected for the reasons of record.

7. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.

8. ☒ For purposes of Appeal, the status of the claim(s) is as follows (see attached written explanation, if any):

   Claim(s) allowed: *None*

   Claim(s) objected to: *None*

   Claim(s) rejected: *1-6, 9, and 10*

9. ☐ The proposed drawing correction filed on _____ a) ☐ has b) ☐ has not been approved by the Examiner.

10. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____

11. ☐ Other:

Deborah Clark
DEBORAH J. R. CLARK
SUPERVISORY PATENT EXAMINER
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DETAILED ACTION

Continued from advisory action:

to a elastin gene that is not functional. It is unclear whether the phrase "b) no functional elastin gene" means only one elastin gene that is not functional or both elastin genes are not functional. If the phrase "b) no functional elastin gene" means only one elastin gene that is not functional, then "a) an elastin gene comprising a null mutation" and "b) no functional elastin gene" are redundant. If the phrase "b) no functional elastin gene" means both elastin genes are not functional, then it is unclear whether one elastin gene that is no functional or both elastin genes are not functional is intended in the claims.

Applicants argue that Sechler reference only teaches a transgenic mouse with mutated rat elastin gene but has normal mouse elastin gene and the motivation of making said transgenic mouse is to produce mice that synthesize a mutated elastin that incorporated into the elastin matrix of normal mouse elastin (amendment, page 4). This is not found persuasive because although the transgenic mice made by Sechler contains mutated rat elastin and normal mouse elastin, the intention of making said transgenic mice is to study the effect of a mutated elastin on the development of a mouse. Sechler also teaches that large deletions on human chromosome 7q, involving the loss of part of the tropoelastin gene, are associated with the vascular disorder SVAS (e.g. p. 162). In combination with the teaching of the complete cDNA sequence of mouse tropoelastin (elastin) gene and that the mutations in the tropoelastin gene are strongly implicated

in SVAS by Wydner, one having ordinary skill at the time the invention was made would have been motivated to produce heterozygous or homozygous transgenic mice or mouse cells having mutated mouse elastin gene in order to study the role of elastin gene in analogous human disorder such as SVAS.

Applicants argue that Reitamo, Sechler and Wydner do not teach elastase and that they can not make obvious a method that requires the use of elastase. This is not found persuasive because Reitamo teaches generating transgenic mice expressing a human elastin promoter/CAT reporter gene construct and injecting IL-10 subcutaneously into said transgenic mice. Reitamo also teach a method of screening a compound which can stimulate the elastin promoter *in vivo or in vitro,* and show IL-10 up-regulates elastin gene expression *in vivo* by CAT assay (transgenic mice skin) and *in vitro* by measuring the elastin mRNA level using Northern analysis. Measuring the effect of a compound on the expression of an elastin gene for screening a drug for treating SVAS would make it obvious for one of ordinary skill to measure the effect of a compound on the elastase activity for the same purpose of screening drug for treating SVAS.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shin-Lin Chen whose telephone number is (703) 305-1678. The examiner can normally be reached on Monday to Friday from 9 am to 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Clark can be reached on (703) 305-4051. The fax phone number for this group is (703) 308-4242.

Questions of formal matters can be directed to the patent analyst, Kimberly Davis, whose telephone number is (703) 305-3015.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist, whose telephone number is (703) 308-0196.

Shin-Lin Chen, Ph.D.